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December 29, 1988

Handwritten signature/initials

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Patent and Trademark Affairs
Sandoz Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936

RE: Patent Term Extension
Application for
U.S. Patent No. 4,282,251
Issued: August 4, 1981

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,282,251, issued August 4, 1981, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be two (2) years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on June 24, 1988 as follows:

$$\begin{aligned}\text{Period} &= 1/2 \text{ (Testing Phase)} + \text{Approval Phase} \\ &= 1/2 (1688) + 714 \\ &= 1558 \text{ days}\end{aligned}$$

Since the regulatory review period began (March 21, 1980) before the patent issued (August 4, 1981), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the extension period. 35 U.S.C. 156(c) (From March 21, 1980 to August 4, 1981 is 501 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: $2189 - 501 = 1688$ days). No determination of a lack of due diligence was made. The exception of 35 USC 156(c)(3) does not operate to reduce the period determined above. The limitation of 35 USC 156(g)(6)(C) applies in the present situation because Patent No. 4,282,251 was issued (August 4, 1981) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Naftin became effective (March 21, 1980), was before the date of enactment, and the product was not approved for commercial marketing or use (February 29, 1988) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,282,251 and Naftin cannot exceed two (2) years under 35 USC 156(g)(6)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,282,251 may be made if filed within one (1) month, not subject to 37 CFR 1.136(a), of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,282,251, a certificate of extension, under seal, for a period of two (2) years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b). Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No. 4,282,251, granted
August 4, 1981 to Daniel Berney
Owner of Record: Sandoz Pharmaceuticals Corporation
Title: TRANS-N-CINNAMYL-N-METHYL-
(1-NAPHTHLMETHYL) AMINE
Classification: 514-655
Product Trade Name: Naftin
Term Extended: 2 years

C E Van Horn

Charles E. Van Horn
Deputy Solicitor
Patent & Trademark Office

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Naftin
FDA Docket # 88E-0183